

TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
UNION OF CONCERNED)
SCIENTISTS)

Pages: 1 through 45
Place: Riverdale, Maryland
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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
UNION OF CONCERNED)
SCIENTISTS)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
March 11, 2004

The parties met, pursuant to the notice, at
2:39 p.m.

ATTENDEES:

For the USDA, Animal & Plant Health Inspection
Service (APHIS) and Biotechnology Regulatory
Services (BRS):

REBECCA BECH, Associate Deputy Administrator
CINDY SMITH, Deputy Administrator
JOHN TURNER, Director of Policy Coordination
LAURA BARTLEY
DAVID BENNETT
JOHN CORDTS
TERRI DUNAHAY
JUDY GARRISON
SUBHASH GUPTA
LEE HANDLEY
NEIL HOFFMAN
SUSAN KOEHLER
SALLY MCCAMMON
VIRGIL MEIER
HALLIE PICKHARDT
BOB ROSE
ROBIN ROSE
CRAIG ROSELAND
MICHAEL WACH
MICHAEL WATSON
CHRIS ZAKARKA

ATTENDEES (Cont'd.)

For Union of Concerned Scientists:

MARGARET MELLON, Director of Food and Environment
Program

JANE RISSLER, Ph.D., Senior Staff Scientist

MR. TURNER: Welcome to our stakeholder

The purpose of these briefings is twofold.

We have here from BRS most of our management

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1 leadership team here at BRS, and I'm pleased to say
2 that John is leading this effort on a full time basis.

3 The second individual, who is most likely a
4 new face with which you're not familiar, Michael Wach
5 just introduced himself. He's a recent BRS hire as an
6 environmental protection specialist within our new
7 environmental and ecological analysis unit that Susan
8 Koehler heads up. In addition to possessing a Ph.D.
9 and an environmental law J.D., Michael brings research
10 experience in plant pathology and weed science, as
11 well as legal experience, working on cases involving
12 NEPA, the Clean Air Act, the Clean Water Act, and
13 other legal statutes.

14 What I'll do at this point is turn this over
15 to John Turner, and he'll provide some additional
16 background information, and then we'll open it up for
17 however you want to spend the rest of your time, if
18 you want to share comments, or if you want to ask us
19 questions, or just have a general give and take.
20 Thank you.

21 MR. TURNER: As you likely know, we recently
22 participated in interagency discussions with EPA, FDA
23 and the White House, which, while concluding that the
24 coordinated framework has provided an appropriate
25 science and risk based regulatory approach for

1 biotechnology, the Plant Protection Act of 2000
2 provides a unique opportunity for APHIS to revise its
3 regulations and to potentially expand our authority,
4 while still leveraging the experience gained through
5 our history of regulation. The new provisions might
6 particularly position us for future advancements of
7 the technology.

8 We concluded those discussions with some
9 general agreement on how our biotech regulatory
10 approach would evolve, but still there is much
11 opportunity for public and stakeholder input as we
12 move forward to develop the specifics of our
13 regulatory enhancements.

14 Given this, what we thought we would like to
15 do in these meetings is have an opportunity to hear
16 your thoughts and to have an informal give and take of
17 ideas. This is a unique opportunity to do this at
18 this time, because we've not yet begun the formal rule
19 making phase of the process, so we're allowed to speak
20 freely and openly and exchange ideas with stakeholders
21 and the public.

22 Our discussions, as you can see, are being
23 professionally transcribed. This is for two reasons:
24 to provide us with an accurate record to facilitate
25 our ability to capture and refer back to your input.

1 Secondly, in the interest of transparency and fairness
2 to all the stakeholders, we will be making available
3 as part of the public record and possibly on our
4 website documentations from all of the stakeholder
5 meetings so that the public and the other stakeholders
6 will each have the benefit of all the discussions that
7 we're having.

8 I want to emphasize that while we're happy
9 to share information on the direction we will likely
10 be taking during the process, that it's an evolving
11 process. Input from the public and stakeholders such
12 as yourself will influence our thinking. In addition,
13 those within USDA, such as our administrator, the
14 undersecretary, our office of general counsel, and the
15 secretary will be expected to provide insightful
16 direction to us as well.

17 So while we value all input, it's important
18 to remember that it's going to evolve. We may have
19 some enthusiastic discussions today about certain
20 things, but it will be an evolving process, so this
21 will change. So, since we don't know exactly what the
22 final regulation will look like, what we can talk
23 about is some of the BRS priority areas that are going
24 to guide us in developing the new regulations.

25 The first is rigorous regulation, which

1 thoroughly and appropriately evaluates and assures
2 safety and is supported by strong compliance and
3 strong enforcement. The second is transparency of the
4 regulatory process and regulatory decision making to
5 stakeholders and the public. We think this is
6 critical for public confidence. The third is we need
7 a science-based system, ensuring that the best science
8 is used to support regulatory decision making to
9 assure safety.

10 Fourth, communication, coordination and
11 collaboration with the full range of stakeholders is
12 vital. Last, I would mention international
13 leadership. We need to ensure that international
14 biotech standards are science based. We need to
15 support international regulatory capacity building,
16 and we have to consider the international implications
17 of the policy and regulatory decisions that we make.

18 As we begin our discussion, I want to let
19 you know for effective transcription, this really
20 doesn't apply if you're both sitting in front of a
21 microphone, is to speak into the microphone. The very
22 first time you speak if you would say your name, and
23 afterwards, that won't be necessary. So with that,
24 I'm happy to turn the discussion over to you.

25 MS. RISSLER: I'm Jane Rissler. First of

1 all, we're very grateful for your outreach efforts.
2 This takes a tremendous amount of your time, and we
3 appreciate being able to talk with you about this
4 important initiative, and we're grateful for the
5 regulatory initiative also. We have felt for years
6 that a change in USDA regs were needed, and we're
7 grateful that you're pursuing this opportunity to take
8 advantage of the Plant Protection Act. It's an
9 opportunity to correct some past deficiencies, to
10 strengthen the ability to act if the environment is
11 threatened, and to prepare for future products.

12 Our approach today, we'll discuss some of
13 the issues we've been thinking about, some that were
14 formed by the pep process on genetically engineered
15 plants. Marty was a part of that effort. I will
16 provide the structure as we go along, and Marty will
17 come in at all sorts of points with other comments.

18 At the outset, I should say that our general
19 goals for USDA regulatory oversight is that the
20 environment be protected from the risk of genetically
21 engineered organisms used in agriculture, both current
22 and future products, that the regulation be based on
23 good science and up-to-date scientific information and
24 through a process that ensures transparency and public
25 involvement in decision making. They pretty much

1 mirror your goals.

2 What I thought we would do is pretty much go
3 through the questions that you laid out in the *Federal*
4 *Register* notice and respond to most of those. I would
5 begin by reiterating what I just mentioned in the
6 introduction. That is that we think that USDA should
7 use the new Plant Protection Act to strengthen its
8 authority and to broaden the scope of regulation of
9 the environmental releases of genetically engineered
10 organisms, not just plants.

11 Now, in terms of genetically engineered
12 plants, using the noxious weed definition from the
13 Plant Protection Act, we would urge USDA to
14 unambiguously declare that all GE plants are subject
15 to review as posing potential noxious weed and/or
16 plant pest risk, getting rid of that ambiguity that
17 was so much a part of the Plant Pest Act and to urge
18 you, of course, to use the authority under the noxious
19 weed definition to consider the environmental risks of
20 genetically engineered plants in decision making,
21 which you have not been able to do under the Plant
22 Pest Act and urge you to assert the authority, to make
23 clear that you will restrict a genetically engineered
24 plant if it turns out that its risks to the
25 environment outweigh or are unreasonable.

1 Now, for nonplant genetically engineered
2 organisms, the issues are not quite as clear to us,
3 and this is where we'd like to ask a question. It
4 looks to us as though you would need to write new
5 implementing regs for transgenics that may pose plant
6 pest risks or may be used as biocontrol agents. But
7 the question to us -- and maybe you can help us
8 understand the Plant Protection Act better -- we see a
9 definition in the noxious weed definition to look at
10 environmental impacts, but we don't see it in the
11 biocontrol definition, and we don't see it in the
12 plant pest definition.

13 Does that mean that this enhanced ability to
14 look at environmental impacts is only for noxious
15 weeds?

16 MS. SMITH: No. I think our intention would
17 be for us to look at anything that came into the
18 system and ask certainly, does it have the potential
19 to be a plant pest and does it have the potential to
20 be a noxious weed. So that's the way that we were
21 approaching it. We think we could look at the
22 environmental risks for everything that would come
23 before us. A lot of this kind of specifics, in terms
24 of a trigger and that kind of thing, that's the kind
25 of thing that we're asking the public input on.

1 MS. MELLON: Just to follow up so something

2 --

3 MS. SMITH: Say your name first.

4 MS. MELLON: Margaret Mellon, Marty Mellon.

5 So if something, if an insect or a nematode came
6 through that was intended for use as a biocontrol
7 agent, you wouldn't regulate it under the biocontrol
8 authority? You would instead try to shoehorn it in as
9 a potential plant pest so that you could take
10 advantage of the substantive --

11 MS. RISSLER: That would be a noxious weed
12 you would, as a non --

13 MS. MELLON: I know, the plant pest is a
14 nonplant.

15 MS. RISSLER: That would, by the
16 environment.

17 MS. SMITH: We haven't nailed down the
18 specifics of how we do it, but our intention is to try
19 to apply this broader scope to everything that came
20 under our review. We're still going to have to look
21 at the specifics of how we're going to do that, but
22 our intention would be to look at the full authorities
23 in the Plant Protection Act and try to apply those to
24 anything that came in. So we'd be asking ourselves,
25 is this something that could be a plant pest, is this

1 something that could be a noxious weed, but the
2 biocontrol is a little different.

3 MS. RISSLER: Looking at the environmental
4 impact, I can't see in the Plant Protection Act where
5 you have authority to look at the environmental
6 implications of a plant pest that are as strong as the
7 environmental implications of a noxious weed.

8 MS. SMITH: Yeah. Let me clarify that.
9 What I meant was, at this point, what we'd know that
10 we would look at is whether something has the
11 potential to be a plant pest and if it has the
12 potential to be a noxious weed, so that means that we
13 should be able to leverage the authorities under the
14 noxious weed, or the scope under the noxious weed
15 definition for everything that we see. We're not sure
16 exactly how the biocontrol will fit it in.

17 MS. RISSLER: It seems to me it would be a
18 stretch if you had an insect. I just want to
19 understand, if you had an insect that comes in and
20 it's a plant pest, I don't see how you can even
21 stretch to say, is it a noxious weed.

22 MR. TURNER: I think you're right. The
23 expanded authority is for plants.

24 MS. MELLOW: It's based only on the word and
25 environment.

1 MS. RISSLER: In the noxious weed
2 definition.

3 MS. MELLON: In the definition of a noxious
4 weed.

5 MR. TURNER: A noxious weed, though, is a
6 plant or a plant product.

7 MS. MELLON: Yes, definitely a plant or a
8 plant product and it even excludes the parasitic
9 plants. So we would just flag that as an issue, that
10 it does seem that the authority in the Plant
11 Protection Act that would allow you to consider the
12 environmental impacts of genetically engineered
13 organisms is restricted to plants, because it derives
14 from the definition of a noxious weed.

15 It would require some quite imaginative
16 stretching, I think, to kind of extend that authority
17 to other kinds of organisms, although plant protection
18 of quarantine, a portion underneath the Plant
19 Protection Act does have implementing regulations on
20 the book that look at insects that are plant pests.

21 MS. MELLON: No. You can look at insects.
22 To be clear, you can look at insects --

23 MS. RISSLER: Yes.

24 MS. MELLON: -- that might be plant pests.

25 Our concern is that there are going to be insects that

1 may turn out not to be plant pests, but will
2 nevertheless have environmental impacts, and that the
3 detection or the assessment of those environmental
4 impacts, under the existing plant pest authority,
5 would not give the agency any power to go out and say
6 we do not approve this. That's our concern, are the
7 inherent limits.

8 Maybe we should back up and say, actually,
9 what you're trying to do is convert quarantine
10 authority into product approval authority, and it's
11 always a difficult thing to do. Rather than having a
12 straightforward statute that brings products to you
13 that you can say, we approve this or we don't, you're
14 still kind of backing in to product authority by
15 trying to say, people, we are somehow going to become
16 aware of products that might be plant pests. The
17 legal essence of our review is the determination that
18 they're not plant pests.

19 MS. RISSLER: It would just be a lot easier
20 if the plant pest definition in the Plant Protection
21 Act mirrored the noxious weed definition in looking at
22 those impacts on resources.

23 MS. MELLON: I guess my only other comment
24 on this issue is that, again, as you are in this early
25 scoping phase, one still needs to consider whether the

1 authority in the Plant Protection Act, expanded as it
2 is, is sufficient to do what you say you want to do
3 and that it may be the case that new legislation is
4 required to provide you with the truly comprehensive
5 authority that you're trying to kind of piece together
6 with this new Plant Protection Act.

7 That may not be true. It's certainly
8 something your lawyers could look into on your behalf,
9 but I think it's an open question.

10 MS. RISSLER: Then, in terms of the second
11 question that you posed about the field testing
12 program, we believe that USDA should grant permits for
13 all field trials and should do so under a risk based
14 tiered system. The tiered system would allow you to
15 use your resources more wisely, that is, focus on the
16 riskier applications and let fewer resources on the
17 lower risked ones. I believe as you noted, the level
18 of information required from the submitter, the level
19 of public involvement, the stringency of confinement
20 requirements would be commensurate with the risk
21 level.

22 In terms of the third question dealing with
23 commercial releases, we believe USDA should require
24 permits for all commercial releases. These are
25 permits, not deregulatory decisions, but permits that

1 could be revoked or conditioned, if necessary. We
2 would foresee currently two tiers, two kinds of
3 commercialization permits. The first might be the
4 standard one, which would allow unrestricted
5 production and sale after a decision based on a
6 conclusion that unrestricted production would not pose
7 any unreasonable risk to the environment or human
8 health.

9 The permit would require reporting to USDA
10 any information on adverse environmental or human
11 health impacts, and it would authorize the agency to
12 revoke the permit based on new information.
13 Admittedly, it would not be an easy finding to revoke
14 a permit, but it should be in the regulations.

15 The conditioned commercialization permit
16 would allow production and sale under certain
17 conditions, to control risks or uncertainties of the
18 product. In effect, this is where we think the
19 commercialization of farm and industrial crops would
20 fall, under this conditioned commercialization permit.
21 It's also where products could be allowed to go
22 forward, as you noted in your *Federal Register* notice,
23 while collecting data that relate to the resolution of
24 minor risks, somewhat as EPA does with the
25 registration conditions on some of the BT crops.

1 Under the conditioned commercialization
2 permit, the decision to grant one would be based on
3 the conclusion that the production under the
4 conditions of the permit would not pose any
5 unreasonable risk to the environment or human health.
6 It would authorize the agency to require monitoring.
7 It would, like the other permit, require the reporting
8 to USDA of any information on adverse environmental or
9 human health impacts, and it would authorize the
10 agency to revoke the permit based on new information
11 or if the permittee violates the conditions.

12 In question 4, you ask about changes in the
13 review of and permit conditions for farm and
14 industrial crops, and you bring up the issues about
15 the impacts of food safety reviews and so on. Our
16 view is that APHIS should adopt a standard of zero
17 contamination of the food supply for farm and
18 industrial crops, and that as a result, the test field
19 trials of these plants must be conducted in such a way
20 to assure this. There would be no need, frankly, to
21 waste resources on food safety reviews.

22 In terms of the regulation of nonviable
23 plant material, we would like to ask a question: what
24 do you have in mind here as nonviable plant material?
25 What we thought of --

1 MS. MELLON: I didn't quite get this.

2 MS. RISSLER: -- we couldn't get it, except
3 we thought about industrial products that EPA reviews
4 under the Toxic Substances Control Act. Would this be
5 your way of saying we want to look at those products?
6 What are you talking about?

7 MS. MELLON: Help us.

8 MS. RISSLER: Nonviable, do you mean dead
9 plant parts?

10 MS. SMITH: Yeah, that's a good question.
11 We don't really have anything in mind under this one.
12 What we're just doing is making the public aware that
13 under the noxious weed definition, under the plant
14 health definition, it was just about that, and it had
15 to be viable. Under a noxious weed, it also includes
16 plant or plant parts.

17 MR. TURNER: Products.

18 MS. SMITH: Products, yeah. So we don't
19 have anything in mind, but we're just saying there's
20 something unique about that definition that we just
21 want to put out there and say, is there something we
22 should consider about having that as a potential
23 source of scope there, something we could consider.

24 MS. MELLON: So the plant products, just as
25 Jane said, might overlap with the TSCA rule that --

1 MS. SMITH: Or with FDA.

2 MS. MELLON: -- reached out, you know, to
3 look at industrials.

4 MR. TURNER: Right.

5 MS. MELLON: Since they would look at the
6 plant products as a product to be regulated under the
7 Toxic Substances Control Act, you might potentially
8 have overlapping authority.

9 MR. TURNER: Yeah, but any part of the plan,
10 once it's not green, once it's not viable anymore,
11 under our current system, we're done. We could do
12 more if you want it, possibly.

13 MS. MELLON: Well, thank you for pointing it
14 out.

15 MS. RISSLER: We couldn't think of it.

16 MS. SMITH: Everyone asks that question.

17 MS. RISSLER: Question 6 asked about the
18 commercial production of pharmaceutical and industrial
19 crops under confined conditions with government
20 oversight. We answered that earlier, that we think it
21 should be a conditioned --

22 MS. MELLON: Commercial permit.

23 MS. RISSLER: -- commercial permit that
24 would trigger the sorts of public notification and
25 involvement that other products do. Now, question 7

1 raises a huge issue, this adventitious presence.

2 There have been attempts, feeble attempts by the
3 government to address it in an OSTP policy a couple
4 years ago. You're trying to address it here. It
5 needs to be addressed in the context of a much larger
6 issue than these regs. We don't know how this is
7 going to intersect with the OSTP policy statement of a
8 couple of years ago. It is --

9 MR. TURNER: It's certainly related to that
10 policy statement, so --

11 MS. RISSLER: It's part --

12 MR. TURNER: -- we're going to establish
13 field testing tiers. One of the criteria we might
14 consider and what confinement standards we put on is
15 whether it had this early safety review of FDA, as an
16 example, which they committed to do in an August 2002
17 document.

18 MS. RISSLER: But have they done any of
19 that?

20 MS. MELLON: Yeah.

21 MR. TURNER: They remain committed to doing
22 that. And we haven't either. We're moving to do
23 these things. We're trying to get a policy in place.

24 MS. MELLON: It does just raise this. It is
25 just a huge issue, as you know, sitting through the

1 advisory committee meeting. Adventitious presence or
2 contamination comes up in many different contexts and
3 has to be, I think, responded to in many different
4 contexts. In some cases, tolerances make sense. In
5 other cases, they don't.

6 You do need to think about lots of classes
7 of materials, those that have never been reviewed,
8 those that have been reviewed and found to be unsafe,
9 those that have been reviewed and have been found to
10 be safe. Those that have been reviewed and found to
11 be safe or unsafe in other countries, I think, is an
12 emerging issue that we're all going to have to deal
13 with. I think our AP policy is going to have to be
14 consistent with what we are going to be willing to
15 live with coming in to this country.

16 But having said that, we do wrestle with
17 this. I think it's the kind of an issue that's big
18 enough that it almost deserves a stakeholder process
19 or some sort of thing where all these folks could get
20 around the table, the trade people and the food
21 people, the regulators, to really think about kind of
22 how it plays out. The OSTP effort was an interesting
23 one, but it doesn't even have a problem statement. It
24 doesn't even say, here's the problem to which this
25 policy might be the answer.

1 So it continues to kind of float out there,
2 unanchored to the real problems. They are a million,
3 if not bigger, dollar problems that people are facing
4 in the international community. I mean I do applaud
5 your trying to take it on, because you can see that
6 it's there, but whether you can take it on in
7 isolation from everybody else, is kind of a
8 government-wide problem.

9 It is a big one, and it's one that we
10 wrestle with in doing our seed report, is that it hit
11 us in the course of doing it. I mean, everything we
12 field tested is potentially out there in the seeds of
13 thought as well as in our commercial bulk product.
14 That's an awful lot of proteins that are out there.
15 Most of them have never been reviewed, much less
16 approved, on the basis of food safety, environmental
17 risk or anything else, so there's nothing small about
18 this problem.

19 MS. RISSLER: I should say we're quite
20 uncomfortable with the notion of exempting low level
21 occurrences of genetically engineered material that
22 hasn't been allowed on the market.

23 MR. TURNER: Irrespective of its food safety
24 status, if it just hadn't completed at APHIS, would
25 you have the same concern?

1 MS. RISSLER: I'm not aware of any. Where
2 is there a food safety review available that says that
3 some of these --

4 MR. TURNER: This is forward looking --

5 MS. MELLON: You mean if one were to come
6 around?

7 MR. TURNER: -- in terms of policy
8 development --

9 MS. RISSLER: If FDA does food safety
10 reviews of everything that's field tested to say
11 whether it would be safe for the food supply under
12 their system.

13 MS. MELLON: I think our general response
14 would be we don't think that that's the right approach
15 to regulating pharmaceutical and industrial crops,
16 this notion that somehow you would review all of them
17 for food safety and then allow them in some -- I think
18 that you would have to assume, then, if they were
19 approved, that they would go into the food supply at
20 low levels. I presume that the government would be
21 prepared to respond if at the levels they went in
22 something went awry.

23 But I really don't think that that's a good
24 approach to pharmaceutical and industrial crops. I
25 think that ties government resources up doing reviews

1 on plants that were never on products and never
2 intended to be in the food supply to begin with, and
3 that that's not a good use of resources. Food safety
4 reviews are not trivial in terms of the resources
5 consumed. So generally, I think we would hope that
6 the issue wouldn't come up.

7 Now for some reason it should, I think we
8 would be more concerned about products that hadn't
9 been reviewed, or certainly among those that had been
10 reviewed and had been found to be unsafe for the food
11 supply than those that had passed a food safety
12 review. But still, you're just in a regulatory
13 thicket, that I don't think that's where we want to
14 be. I think it's much better to really look hard at
15 that pharmaceutical and industrial production and
16 figure out how to really keep those substances out of
17 the food supply.

18 MR. TURNER: They may be separate highways
19 which you do for pharm and industrials that will be
20 due for products which are bound for food and feed, so
21 we may answer those separate ways.

22 MS. MELLON: Well, and there's always the
23 option of not using food crops. I mean, now there's
24 one big way that I think you could accomplish a big
25 part of the goal of preventing contamination.

1 MS. SMITH: Just to clarify on No. 7, where
2 we're referring to the potential for adventitious
3 presence, we're not including pharmaceuticals and
4 industrials in that. We're only including --

5 MS. MELLON: You would only be looking at --

6 MS. SMITH: Food parts.

7 MS. MELLON: So that's an important --

8 MS. SMITH: But your comments are relevant
9 back under No. 4, where one of the things we're going
10 to look at is whether going through a food safety
11 evaluation and the results of that should have an
12 impact on the confinement conditions that we put in
13 place.

14 MS. MELLON: Right, and I understand it, but
15 I hope we don't go there.

16 MS. RISSLER: Under the adventitious
17 presence, do you think FDA could move toward a food
18 safety review of every substance that is field tested
19 under APHIS?

20 MR. TURNER: I shouldn't answer much for
21 FDA, but if you look at it on a protein basis versus a
22 protein event by crop basis, it's not near as many.
23 The compositional analysis, they said, in that paper
24 is not really important, because it's at a low level.
25 It's the toxicity allergenicity, so it's an

1 abbreviated review that they --

2 MS. MELLON: They do it on the BTs and let
3 it go. I think that that's true. It may be possible
4 for them to do it. It's not appealing, but I wouldn't
5 rule it out, again, depending on the context of what
6 else is getting into the food supply, but I now
7 remember that. If you think about just doing the
8 early reviews, like on BT toxins, as class, the
9 resource issue is addressed somewhat.

10 MS. RISSLER: So you would rid the argument
11 that the exposure is so low that the hazard component
12 would have to be really large before that would be a
13 risk?

14 MR. TURNER: Not necessarily, but you don't
15 have to do the entire compositional analysis. A
16 slight change in vitamin of something considered a
17 half percent is a wash.

18 MS. RISSLER: Well, I think the devil is in
19 the details, isn't it?

20 MR. TURNER: This is an FDA issue besides
21 that.

22 MS. MELLON: Yeah. It is true.

23 MS. RISSLER: Number 8 raises some
24 interesting issues. There is this exemption, or to
25 exempt or expedite review of low risk engineered

1 commodities that we would be importing, that they
2 would have necessarily regulatory approvals in the
3 country of origin and not intended for propagation in
4 the U.S. I think USDA dealt with a couple of
5 applications like that, the canola that was brought in
6 from Canada for processing, I think. It was not to be
7 propagated, some years ago.

8 Here are the problems: who says they are
9 low risk? Do all countries have a regulatory scheme
10 that we would trust to say that it's low risk? I
11 mean, they're not all going to be Canada. So it is a
12 tricky issue how to define what these necessary
13 regulatory approvals will be and what standards they
14 have met in coming to those decisions.

15 MS. MELLON: But it's a fundamental issue.
16 You've got to deal with it somehow. If you're going
17 to deal in an export/import economy, we have to make
18 decisions. If we're going to ask people to accept our
19 regulations, they're going to ask us to accept their
20 regulations. So I don't reject the idea that you
21 would make decisions about the use of products in this
22 country on the basis of reviews done elsewhere. That
23 is not tenable to do otherwise, but it is going to be
24 difficult, especially since you all are as involved as
25 anybody in the world in capacity building, so you know

1 the kind of variation and regulatory capacity across
2 the globe.

3 To even start to do it, I guess you would
4 have to rank other countries in terms of the quality
5 of the reviews that they do and then give their
6 products differential treatment. I don't know how
7 that would play in the international environment.
8 It's not a bad idea that you would take -- at some
9 point we have to begin to take other folks' regulatory
10 systems. We have to grant them some deference in
11 terms of what we would do. We can't assume that the
12 rest of the world, what it does, doesn't count.

13 MS. RISSLER: Number 9, exempting
14 genetically engineered plants from interstate movement
15 restrictions because -- well, we think it's fine. It
16 relates to then next question, then.

17 MS. MELLON: Arabidopsis. Go, go, go.

18 MS. RISSLER: I mean an Arabidopsis-like.

19 MS. MELLON: Yes.

20 MS. RISSLER: We think that the regulatory
21 requirements on interstate movement ought to
22 encourage, not discourage, research, so we would see
23 that as a lessening of regulatory oversight. Now No.
24 11, we don't know. We don't know container
25 requirements, so we will pass. We don't have an

1 opinion.

2 I would like to make two other comments in
3 this, to reiterate that the regs should delineate
4 provisions for meaningful public involvement,
5 notification availability of information and
6 opportunities to comment. Secondly, we're reiterating
7 something we've said on many occasions, and that is
8 that there is a need for a scientific advisory
9 capacity.

10 We would urge you to explore providing for a
11 scientific advisory committee mechanism in the regs,
12 so that it would facilitate your use of outside
13 scientists and would also facilitate the public's
14 awareness of how you are using outside scientific
15 expertise and I think would promote confidence in your
16 use of science in making decisions.

17 That is what we have to say.

18 MS. SMITH: Wonderful. Can we ask you some
19 questions?

20 MS. MELLON: Sure.

21 MS. SMITH: Okay. Who has got questions?

22 MS. RISSLER: How many of these have you
23 done? You're pretty tired, I bet.

24 MS. SMITH: I think we're --

25 MR. TURNER: Twenty the first week.

1 MS. SMITH: Yeah, the first week we did 20.

2 Then this is the third one today, and we've got just
3 two more tomorrow.

4 MS. RISSLER: Oh, my word. We're 23 out of
5 25. You're pooped.

6 MS. SMITH: We're trying to get an organic
7 group to get in as well but haven't been able to get a
8 call back. I think we're getting close to the end.
9 We're good this week. If you got us on Friday of the
10 first week --

11 MS. RISSLER: Twenty.

12 MS. SMITH: -- it's a good thing that you've
13 got it all written down.

14 MS. MELLON: That's truly, truly amazing.

15 MS. SMITH: So what kind of questions do we
16 have? I know we have lots.

17 MS. KOEHLER: Susan Koehler. I'm interested
18 in your comment on No. 9. That's with regards to
19 exempting interstate movement restrictions.

20 MS. RISSLER: Yeah.

21 MS. KOEHLER: Are there similar genetically
22 engineered plants that you can think of, or other
23 organisms that you can think of, that we ought to be
24 exempting from interstate movement that would
25 particularly encourage research, not impede it,

1 anyway?

2 MS. RISSLER: I don't know the research well
3 enough. I can't think of anything.

4 MS. MELLON: I mean, you have to ask the
5 people who are doing the research.

6 MS. RISSLER: Who are doing the research,
7 scientists.

8 MS. MELLON: But certainly model plants,
9 like Arabidopsis that are not agricultural crops by
10 any stretch of the imagination.

11 MS. RISSLER: What else are people using
12 these days?

13 MS. MELLON: I don't know what they're
14 using.

15 MR. TURNER: It seems like tobacco has been
16 used a lot as a crop and not a food crop.

17 MS. MELLON: Yeah. That would have been
18 harder, but --

19 MR. HOFFMAN: A lot of the research is on
20 crops and is the --

21 MS. MELLON: Of course, yeah.

22 MR. HOFFMAN: -- genomics programs, so
23 they're using cotton and maize. There's a lot of
24 money in those two crops, soybeans, so I don't know.

25 MS. MELLON: But actually, I think that you

1 would want to look to requirements that are relaxed to
2 the extent, that are commensurate with the amounts
3 that are being moved, and usually, you're going to be
4 talking about relatively -- I mean I would say
5 minuscule amounts to the amounts that you're going to
6 be talking about in terms of field testing or
7 something like that. Even for food crops, it's just
8 reasonable to take small amounts into account, but --

9 MS. RISSLER: What do people shift? If
10 you're this interstate movement of Arabidopsis, now
11 there wouldn't be any container requirements, that
12 they would be exempt, so you could throw genetically
13 engineered Arabidopsis in an envelope and mail it.

14 MR. TURNER: You know, it's an open question
15 now. It's a picture. You could, I suppose, still
16 hold them to container requirements, but reduce some
17 of the paperwork over the shipments.

18 MS. RISSLER: See, we're just not involved
19 in those kinds of -- if we were doing research, we
20 would be, but we don't even appreciate how onerous
21 they are.

22 MR. TURNER: It just has the academic
23 community in mind.

24 MS. MELLON: Yes, well, they're a very
25 important group. They'd certainly know much better

1 than we, but what they are likely to move and what
2 they'd want to move --

3 MS. MCCAMMON: Sally McCammon. You said
4 that you would consider importing commodities into
5 this country with an expedited review or an exempted
6 review, particularly for the environmental aspect, if
7 we either recognized another country's review process
8 or admit certain international standards. So for
9 instance, canola coming in from Canada, if it had gone
10 through their review system or a system that we
11 recognized, that would be acceptable if it had been
12 thought through.

13 MS. RISSLER: You're talking about ones that
14 are going to be processed only, not propagated?

15 MS. MCCAMMON: Right. Correct.

16 MS. MELLON: I think the case where you'd be
17 most likely to use the expedited review would be one
18 where a food safety review had been done somewhere
19 else, and it came into this country to be crushed or
20 processed in some way so that there would be no
21 environmental risks to take account of.

22 You certainly would not want as a general
23 matter to look forward to approving products that were
24 sent into this country that were still viable on the
25 basis of an environmental risk done elsewhere, because

1 environmental risks, by their very nature, are context
2 and habitat dependent, so if someone had done a review
3 on a squash in a country where there were no relatives
4 of squash, they're going to come up with no
5 environmental risk in that country, but of course,
6 they're not going to have considered that we have lots
7 of squash relatives here.

8 So it is the environmental risk and the
9 environmental assessment where you'd be less inclined
10 to kind of accept it on the basis of some kind of
11 general accreditation of another country's review
12 system.

13 MS. RISSLER: The food safety review.

14 MS. MELLON: But a food safety review is
15 likely to --

16 MS. RISSLER: Unless you have special --

17 MS. MELLON: Again, some populations have a
18 kind of different kind of allergenicity profile from
19 others, so that might need to be something that you
20 would take into account, but that would be the more
21 likely situation where you'd look at it. It would be
22 appropriate for an expedited review.

23 For example, I think one of the issues that
24 came up in reverse with regard to Zimbabwe is that the
25 reviews done on maize on the U.S. envision the use of

1 corn for actually direct ingestion along the lines of
2 the U.S. diet, which means an occasional ear of sweet
3 corn in the summer. In Zambia, people eat corn every
4 single day, and it's a very large part of their diet.

5 So there are situations where the kind of a
6 risk assessment that was done, even for food safety
7 purposes in one country, might not necessarily be
8 appropriate for another country, but certainly
9 toxicity type stuff, I think you'd be on fairly sound
10 ground.

11 MS. MCCAMMON: Well, maybe a small follow up
12 and then we'll -- on the environmental side, if a
13 country had very similar environments as ours for a
14 particular crop, then it would be appropriate to
15 consider that.

16 MS. RISSLER: Like southern Canada versus
17 northern --

18 MS. MCCAMMON: North Dakota or something.

19 MS. MELLON: Yeah.

20 MS. MCCAMMON: Okay. Thanks.

21 MR. ROSELAND: You encourage us to have
22 meaningful public comment on our new regs. I was
23 wondering if you could pin that down with some
24 specific mechanisms that would help us do that in a
25 way that we might not otherwise do.

1 MS. RISSLER: Well, actually, I was
2 referring more to meaningful public regs that would
3 allow meaningful public comment for products that come
4 through the new regulatory system. You're thinking
5 about when it's time to do the proposed rule under
6 this --

7 MR. ROSELAND: Well, either one. I mean,
8 we're always looking for mechanisms, but what would
9 they be, if you could dream one up for us?

10 MS. RISSLER: Well, built on our experience
11 over the years, one is notification that there's an
12 application for a product, that information is
13 available on that product and that it be available in
14 a timely manner, that there will be at some point an
15 opportunity to comment on the risk of that product. I
16 think it's always helpful to have an assessment from
17 the reviewing agency to also look at, to judge the
18 quality of the assessment so that there are
19 opportunities for public comment, timely release of
20 information, as little CBI as possible.

21 MS. MELLON: In terms of going about this
22 major rule making that you're envisioning, you're off
23 to a pretty phenomenal start. I mean I can't think of
24 any other agency that has ever engaged in a process
25 similar to the one we are now engaged in to actually

1 reach out to people before you started writing, that
2 we'll see what people care about and what kinds of
3 suggestions that they have. So you're breaking some
4 ground yourselves.

5 MS. RISSLER: Which we hope becomes better
6 trodden by other agencies.

7 MS. MELLON: Yes. But it is important,
8 because as your introductory remarks indicated, of
9 course, you're well aware that at some point the rule
10 development system is shut down. You know, you kind
11 of take in a lot of public comment and then you start
12 working on it yourself, and then you really have to
13 kind of shut off the valves of input. So taking the
14 initiative in this case to actually get input at that
15 early stage is important.

16 MR. TURNER: We do plan other opportunities.
17 There will be a draft EIS out for comment.

18 MS. MELLON: I know, and that in itself has
19 a lot of process.

20 MR. TURNER: Then a proposed rule, and we're
21 considering having public meetings maybe at that time.

22 MS. MELLON: And EIS has envisioned that you
23 would send notices out and invite input from sister
24 agencies, or at least most of them.

25 MR. TURNER: Yeah, that will be a part of

1 the process.

2 MS. MELLON: I mean in general, I want to
3 reiterate how important I think it is that somebody in
4 the federal government actually takes seriously the
5 responsibility to oversee the release of genetically
6 engineered organisms in the categories you're talking
7 about. You're talking about insects. That's just an
8 enormous category. Nematodes. There's a lot out
9 there, in addition to virtually all plants.

10 Up until this point, there has not been
11 evidence that the federal government was willing to
12 actually step up to the plate and simply say, we're
13 looking at all genetically engineered organisms, and
14 we're going to assure that none of them go into the
15 environment without an assessment. The overall scope
16 of your project and your willingness to do it with
17 this level of seriousness is really to be applauded,
18 and it's very important. It's very important for the
19 environment, but it's very important for the success
20 of both industries and projects that depend on genetic
21 engineering.

22 They are at a juncture where I think it's
23 quite reasonable to say that they're going to have a
24 very hard time going forward, for lots of reasons.
25 But they certainly, I think, are not going to be able

1 to go forward. Genetically engineered animals and
2 insects and other organisms that are not clearly
3 regulated in the world, and the country that is the
4 biggest proponent of genetically engineered organisms,
5 those industries based on those products will not go
6 forward, I think, from now on, unless everybody in the
7 U.S. and outside the U.S. is sure that there is going
8 to be a credible regulation.

9 You're about something that is very
10 important, and lots, lots rests on whether you can put
11 together credible regulatory programs where really
12 none have existed before.

13 MS. SMITH: John, are you feeling under
14 pressure?

15 MS. MELLON: And John is a great choice to
16 lead this. I want to say that as well.

17 MS. SMITH: Okay. I just want to point out
18 that the other agency folks are here. Why don't we
19 just maybe take one or two more questions and wrap
20 this up. We'll just take a two minute break real
21 quick so we can get everyone kind of in the same area.
22 Do we have a final question? Then hopefully, we can
23 pick your brains a little bit.

24 MR. HOFFMAN: I have one little question.
25 Earlier, you were talking about commercialization,

1 particularly with it relating to plant made
2 pharmaceuticals. I'm just wondering when you think of
3 commercialization, what are you thinking of? Let me
4 just put this in some context. Many of these products
5 can be commercialized on --

6 MS. MELLON: A very small scale.

7 MR. HOFFMAN: -- one or two acres. So when
8 we try to regulate based on the risks, a two acre plot
9 is a two acre plot. When you talk about
10 commercialization, are you referring to a large scale,
11 or are there other aspects you want us to consider?

12 MS. MELLON: Right. We appreciate the fact
13 that you can commercialize these on a small scale, but
14 I still think the right trigger that is appropriate
15 that pharmaceutical crops even produced on small
16 acreage are treated, are granted conditioned permits,
17 based on the trigger of commercialization, actually
18 selling it in commerce. It's not necessarily based on
19 risk, but I think it's important that people know the
20 kind of fate of products in the environment and that
21 it's the most straightforward way of kind of handling
22 all these things in the same way.

23 I don't understand any easier trip point for
24 issuing a conditioned permit that would not change
25 over time that's any better than the point at which

1 people are actually selling the product on the
2 marketplace. Otherwise, you have to come up with some
3 sort of an acreage trip, and you would say, well, over
4 5 acres or over 10 acres. That doesn't seem to me to
5 be any easier. I don't understand the advantage.

6 So I do understand the problem, or the
7 issue, but I would still think the most
8 straightforward approach to regulation is to be able
9 to say that all of the products that are available in
10 the commercial marketplace have been issued
11 conditioned permits and that relatively speaking, the
12 amount of public input and public notification that
13 accompanies commercialized crops, whatever their use,
14 is about the same. But it's an issue.

15 MR. HOFFMAN: What we seeing happening is
16 some of these products are being very tailored. It
17 may be that they just go out there once. It's
18 actually an antibody for one person for treating one
19 -- it's really tailored to an individual --

20 MS. MELLON: Really?

21 MR. HOFFMAN: That's correct.

22 MS. MELLON: Whoa.

23 MR. HOFFMAN: So what we're talking about
24 potentially --

25 MS. MELLON: One person would buy an

1 antibody triggered for herself?

2 MR. HOFFMAN: That's correct.

3 MS. MELLON: Gosh. This must be the same
4 person that got them to produce Missiplicity.

5 MR. HOFFMAN: So the idea is that, and when
6 I've inquired, well, that seems very expensive for a
7 company to develop something along those lines, the
8 feedback that I was given is, well, when you think of
9 what it costs the whole health care industry for this
10 person to suffer with that kind of treatment, you're
11 talking about approaching hundreds of thousands to a
12 million dollars, and that if there's treatment that
13 you can devise that's \$100,000, it becomes cost
14 effective.

15 So I think what we will be seeing in the
16 future as we move down is that you're going to be
17 having products that are not commodity products but
18 that they're going to be very limited, very
19 customized.

20 MS. MELLON: Well, yeah.

21 MR. HOFFMAN: I just put that out there for
22 --

23 MS. MELLON: I mean, that's a nice legal
24 question about what is commercialization. Is it
25 really commercialization if you've actually produced

1 something on a contract basis for an individual? It
2 certainly is news to me. It would require perhaps
3 some more thinking. But I do think it's important,
4 however one would decide to deal with these, this set
5 of activities, that there be sufficient public notice
6 about what people are doing that we know that. I
7 think it's important.

8 Again, these are kind of broad contrasts,
9 but I don't think it would be a good idea for the
10 system to be set up in such a way that there could be
11 hundreds of these antibodies being produced at
12 different levels and that people would never really
13 know about that, because it would all still be covered
14 under field tests or some sort of exemptions that
15 might emerge under the field test provisions. The
16 public ought to be able to understand the way these
17 products are being used, so whatever decision was
18 made, I wouldn't want it made in the direction of
19 allowing a lot of very small activity to kind of go
20 forward under the radar screen.

21 But I would also point out that a
22 conditioned permit is not necessarily a resource-
23 intensive activity, but at least in our minds, it does
24 have notification and process accoutrements that make
25 it valuable. Even in the case of things like that,

1 you'd certainly want the ability to revoke the permit
2 or the permission, however it was legally styled, if
3 something were to go wrong.

4 MS. SMITH: Okay. In the interest of time,
5 we've got other people here on another subject.

6 MS. MELLON: Okay.

7 MS. SMITH: A related subject we're going to
8 talk about.

9 MS. MELLON: Yes.

10 MS. SMITH: We want to thank you for your
11 comments and your time --

12 MS. MELLON: Thank you.

13 MS. SMITH: -- for your very thoughtful and
14 direct comments. This is really very useful to us,
15 and we look forward to continuing to being able to
16 talk to you and having this be a dialogue up until the
17 appropriate point, we would be so grateful.

18 MS. MELLON: Great.

19 (Whereupon, at 3:40 p.m, the meeting was
20 concluded.)

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REPORTER'S CERTIFICATE

TITLE: Stakeholders Meetings
(Union of Concerned Scientists)

DATE: March 11, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: March 11, 2004

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